

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

SEPRACOR INC.,

Plaintiff,

v.

DEY, L.P. and DEY, INC.,

Defendants.

**C.A. No. 06-113-KAJ**

**PLAINTIFF SEPRACOR INC.'S REPLY TO  
DEFENDANTS DEY, L.P. AND DEY, INC.'S COUNTERCLAIMS**

Plaintiff Sepracor Inc. ("Sepracor") hereby responds to each of the numbered paragraphs of the Counterclaims of Defendants Dey, L.P. and Dey, Inc. (collectively "Dey").<sup>1</sup> Sepracor expressly denies any allegations not admitted herein.

**JURISDICTION AND VENUE**

40. Sepracor admits that Dey's Counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* The remaining allegations of paragraph 40 of Dey's Counterclaims aver legal conclusions and, as such, Sepracor is not required to admit or deny it.

41. Sepracor admits the allegations set forth in paragraph 41 of Dey's Counterclaims.

42. Sepracor admits the allegations set forth in paragraph 42 of Dey's Counterclaims.

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<sup>1</sup> Herein, Sepracor's numbered paragraphs track those of Dey's Counterclaims which begin with paragraph number 40 and end with paragraph number 64.

43. Sepracor admits the allegations set forth in paragraph 43 of Dey's Counterclaims.

#### **THE PARTIES**

44. With regard to paragraph 44 of Dey's Counterclaims, Sepracor admits that it claimed the following: Dey, L.P. is a limited partnership organized under the laws of Delaware, having its principal place of business at 2751 Napa Valley Corporate Drive, Napa, California; Dey, L.P.'s registered office in Delaware is located at 1209 Orange Street, Wilmington, Delaware, 19801; and Dey, L.P.'s registered agent for service of process in Delaware is the Trust Company, 1209 Orange Street, Wilmington, Delaware 19801.

45. With regard to paragraph 45 of Dey's Counterclaims, Sepracor admits that it claimed the following: Dey, Inc. is a corporation organized under the laws of Delaware, having its principal place of business at 2751 Napa Valley Corporate Drive, Napa, California; Dey, Inc.'s registered office in Delaware is located at 1209 Orange Street, Wilmington, Delaware, 19801; and Dey, Inc.'s registered agent for service of process in Delaware is the Trust Company, 1209 Orange Street, Wilmington, Delaware 19801.

46. Sepracor admits the allegations set forth in paragraph 46 of Dey's Counterclaims.

#### **PATENTS-IN-SUIT**

47. Sepracor admits the allegations set forth in paragraph 47 of Dey's Counterclaims.

48. Sepracor admits the allegations set forth in paragraph 48 of Dey's Counterclaims.

49. Sepracor admits the allegations set forth in paragraph 49 of Dey's Counterclaims.

50. Sepracor admits the allegations set forth in paragraph 50 of Dey's Counterclaims.

51. Sepracor admits the allegations set forth in paragraph 51 of Dey's Counterclaims.

#### **ACTS GIVING RISE TO THE ACTION**

52. Sepracor admits the allegations set forth in paragraph 52 of Dey's Counterclaims.

53. With regard to paragraph 53 of Dey's Counterclaims, Sepracor admits that according to the Food and Drug Administration, Center for Drug Evaluation and Research, Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") listings, levalbuterol hydrochloride inhalation solutions, or methods of use, are claimed in U.S. Patent Nos. '755, '994, '090, '002, and '993.

54. Sepracor admits the allegations set forth in paragraph 54 of Dey's Counterclaims.

55. Sepracor admits the allegations set forth in paragraph 55 of Dey's Counterclaims.

56. Sepracor admits the allegations set forth in paragraph 56 of Dey's Counterclaims.

57. Paragraph 57 of Dey's Counterclaims avers a legal conclusion and, as such, Sepracor is not required to admit or deny it. Sepracor denies the allegation that Dey has not, does not, and will not infringe any valid and/or enforceable claim of the '755, '994, '090, '002, and '993 Patents.

#### **FIRST COUNTERCLAIM**

58. With regard to paragraph 58 of Dey's Counterclaims, Sepracor restates and incorporates by reference its responses to each of the foregoing allegations as though fully set forth herein.

59. Paragraph 59 of Dey's Counterclaims avers a legal conclusion and, as such, Sepracor is not required to admit or deny it. Sepracor denies the allegation that Dey does not infringe any claim of the '755, '994, '090, '002, and '993 Patents.

60. Sepracor denies the allegations set forth in paragraph 60 of Dey's Counterclaims.

61. Sepracor denies the allegations set forth in paragraph 61 of Dey's Counterclaims.

#### **SECOND COUNTERCLAIM**

62. With regard to paragraph 62 of Dey's Counterclaims, Sepracor restates and incorporates by reference its responses to each of the foregoing allegations as though fully set forth herein.

63. Paragraph 63 of Dey's Counterclaims avers a legal conclusion and, as such, Sepracor is not required to admit or deny it.

64. Sepracor denies the allegations set forth in paragraph 64 of Dey's Counterclaims.

## **DEFENSES**

### **FIRST DEFENSE**

Dey's Counterclaims fail to state a claim upon which relief can be granted.

### **SECOND DEFENSE**

The making, using, selling, offering to sell, or importing of Dey's Levalbuterol Inhalation Solutions does and will, if marketed, infringe one or more claims of each of the '755, '994, '090, '002, and '993 Patents (the "Sepracor Patents").

### **THIRD DEFENSE**

The claims of the Sepracor Patents are valid under all conditions of patentability set forth in Title 35 of the United States Code.

### **PRAYER FOR RELIEF**

WHEREFORE, Sepracor denies that Dey is entitled to any of the relief requested in Dey's Prayer for Relief and respectfully requests that the Counterclaims of Dey be dismissed with prejudice; and that judgment be entered in favor of Sepracor as follows:

(A) A judgment declaring that Dey has infringed and that Dey's making, using, selling, offering to sell and/or importing of Dey's Levalbuterol Inhalation Solutions will infringe one or more claims of each of the Sepracor Patents;

(B) A judgment declaring that the effective date of any approval of Dey's ANDA No. 77-800 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) for Dey's Levalbuterol Inhalation Solutions must be no earlier than the expiration date of the last to expire of the infringed Sepracor Patents.

(C) A permanent injunction enjoining Dey, its officers, agents, attorneys, and employees, and anyone acting in concert with them, from making, using, selling, offering to sell, and/or importing Dey's Levalbuterol Inhalation Solutions until after the expiration of the last to expire of the infringed Sepracor Patents.

(D) A judgment that Dey's infringement of the Sepracor Patents was and is willful, and that Sepracor is entitled to its reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

(E) A judgment awarding Sepracor costs and expenses in this action.

(F) Such other and further relief as the Court deems just and equitable.

**DEY'S JURY DEMAND**

Sepracor has concurrently filed a motion, with an accompanying opening brief in support thereof, to strike Dey's improper demand for a trial by jury.

July 7, 2006

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**CERTIFICATE OF SERVICE**

The undersigned counsel certifies that, on July 7, 2006, he electronically filed the foregoing document with the Clerk of the Court using CM/ECF, which will send automatic notification of the filing to the following:

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The undersigned counsel further certifies that, on July 7, 2006, copies of the foregoing document were sent by email and hand to the above local counsel and by email and first class mail to the following non-registered participant:

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